

REMARKS***Claim Amendments***

After entry of this amendment, claims 1-2, 5-11, 16-18, 21-23, 25-29, 42-43 and 47 will be pending in this application. Claims 1, 16, 18 and 25-29 have been amended. Support for these amendments can be found throughout the specification, particularly at ¶¶ 12, 33 and 37 and in Example 12 of US2002/0132771.

Rejection Under 35 U.S.C. §112, ¶1

The Examiner has rejected claims 1-2, 5-11, 16-18, 21-23, 25-29 and 42-47 as lacking enablement. The Examiner alleges that the above recited claims lack enablement because one of skill in the art could not synthesize, without undue experimentation, an antibody that binds to the same epitope to which a monoclonal antibody produced by a hybridoma that has ATCC Designation Number PTA-975 specifically binds. The Examiner appears to base this rejection on the fact that the epitope to which the monoclonal antibody produced by hybridoma PTA-975 binds comprises an allegedly unidentified carbohydrate moiety.

Applicant traverses the enablement requirement. However, in order to expedite prosecution, Applicant has amended the claims to recite a method for treating a mammal bearing a tumor comprising administering an antibody or antigen binding fragment thereof that binds to an epitope of MUC-1 comprising a peptide and a carbohydrate, wherein said peptide portion comprises the amino acid sequence DTRPAP, and wherein said antibody or antigen binding fragment thereof binds preferentially to glycosylated MUC-1. Applicant respectfully submits that the claims, as amended, are enabled. A person of skill in the art could readily practice the claimed invention without undue experimentation, using the methods disclosed in the specification and readily known in the art.

For example, a person of skill in the art could readily make antibodies which bind to an epitope of MUC-1 comprising the amino acid sequence DTRPAP. This could be done by immunizing an animal using a glycosylated MUC-1 (or a cell expressing glycosylated MUC-1) as an antigen, harvesting and immortalizing antibody-secreting splenocytes, and subsequently screening and selecting clones which secrete antibodies which bind to an epitope of MUC-1

comprising the amino acid sequence DTRPAP. These methods are disclosed in Example 1 of the specification, and are routine in the art.

A person of skill in the art could also determine whether an antibody (or an antigen binding fragment thereof) which binds to an epitope of MUC-1 comprising the amino acid sequence DTRPAP, binds preferentially to glycosylated MUC-1 using no more than routine experimentation. For example, this can be done by comparing the binding of the antibody (or antigen binding fragment thereof) to glycosylated MUC-1 and unglycosylated MUC-1 as disclosed in Example 12 of the specification.

In view of the arguments and amendments presented herein, Applicant respectfully requests that the Examiner withdraw this enablement rejection.

Conclusion

Applicant believes no fee, other than the accompanying fee for a three-month extension of time under 37 C.F.R. 1.136(a), is due with this response. However, if an additional fee is due, please charge our Deposit Account No. 18-1945, under Order No. AREX-P03-002.

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Respectfully submitted,

By 

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